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11/01/01
Date

Katherine K. Lemon
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Katherine A. HIGH

Serial No.: 09/880,702 Group Art Unit: 1615

Filing Date: June 13, 2001 Examiner: Unassigned

Title: METHODS FOR ADMINISTERING RECOMBINANT ADENO-ASSOCIATED VIRUS VIRIONS TO HUMANS PREVIOUSLY EXPOSED TO ADENO-ASSOCIATED VIRUS

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

United States Patent No. 5,858,351 issued January 12, 1999 to Podsakoff et al.;

United States Patent No. 6,093,392 issued July 25, 2000 to High et al.;

Berns and Linden, "The Cryptic Life Style of Adeno-Associated Virus," *Bioessays* 17:237-245 (1995);

Burton et al., "Coexpression of Factor VIII Heavy and Light Chain Adeno-Associated Viral Vectors Produces Biologically Active Protein," *Proc. Natl. Acad. Sci. U.S.A.* 96:12725-12730 (1999);

Chao et al., "Several Log Increase in Therapeutic Transgene Delivery by Distinct Adeno-Associated Viral Serotype Vectors," *Mol. Ther.* 2:619-623 (2000);

Chiorni et al., "Cloning of Adeno-Associated Virus Type 4 (AAV4) and Generation of Recombinant AAV4 Particles," *Journal of Virology* 71:6823-6833 (1997);

Chirmule et al., "Humoral Immunity to Adeno-Associated Viurs Type 2 Vectors Following Administration to Murine and Nonhuman Primate Muscle," *Journal of Virology* 74(5):2420--2425 (2000).

Erles et al., "Update on the Prevalence of Serum Antibodies (IgG and IgM) to Adeno-Associated Virus (AAV)," *Journal of Medical Virology* 59:406-411 (1999);

Flannery et al., "Efficient Photoreceptor-Targeted Gene Expression *in vivo* by Recombinant Adeno-Associated Virus," *Proc. Natl. Acad. Sci. U.S.A.* 94:6916-6921 (1997);

Flotte et al., "Stable *in vivo* Expression of the Cystic Fibrosis Transmembrane Conductance Regulator with an Adeno-Associated Virus Vector," *Proc. Natl. Acad. Sci. U.S.A.* 90:10613-10617 (1993);

George-**Fries** et al., "Analysis of Proteins, Helper Dependence, and Seroepidemiology of a New Human Parovirus," *Virology* 134:64-71 (1984);

Halbert et al., "Successful Readministration of Adeno-Associated Virus Vectors to the Mouse Lung Requires Transient Immunosuppression During the Initial Exposure," *Journal of Virology* 72:9795-9805 (1998);

Manning et al., "Transient Immunosuppression Allows Transgene Expression Following Readministration of Adeno-Associate," *Human Gene Therapy* 9:477-485 (1998);

Moskalenko et al., "Epitope Mapping of Human Anti-Adeno-Associated Virus Type 2 Neutralizing Antibodies: Implications for Gene Therapy and Virus Structure," *Journal of Virology* 74:17610-1761-1766 (2000);

Nakai et al., "Isolation of Recombinant Adeno-Associated Virus Vector-Cellular DNA Junctions from Mouse Liver," *Journal of Virology* 73(7):5438-5447 (1999);

Snyder et al., "Persistent and Therapeutic Concentrations of Human Factor IX in Mice After Hepatic Gene Transfer of Recombinant AAV Vectors," *Nat. Genet.* 16:270-276 (1997); and

Su et al., "Adeno-Associated Viral Vector-Mediated Vascular Endothelial Growth Factor Gene Transfer Induces Neovascular Formation in Ischemic Heart," *Proc. Natl. Acad. Sci. U.S.A.* 97:13801-13806 (2000).

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date: 11/01/01

By: _____
Roberta L. Robins
Registration No. 33,208

ROBINS & PASTERNAK LLP
90 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: 650-325-7812
Facsimile: 650-325-7823

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1615 #3. 5-29-02 attachment

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11/01/01 Patricia K Jones
Date Signature

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TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is an Information Disclosure Statement, including a Form PTO-1449 and copies of the cited references. It is believed that no fee is due.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648.

Respectfully submitted,

Date: 11/1/01 By:
Roberta L. Robins
Registration No. 33,208

ROBINS & PASTERNAK LLP
90 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 325-7812
Facsimile: (650) 325-7823